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SUN, Jianbo [CN/US]: 130 Milford Street #21, Rochester, NY 14615 (US).

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(88) Date of publication of the international search report:
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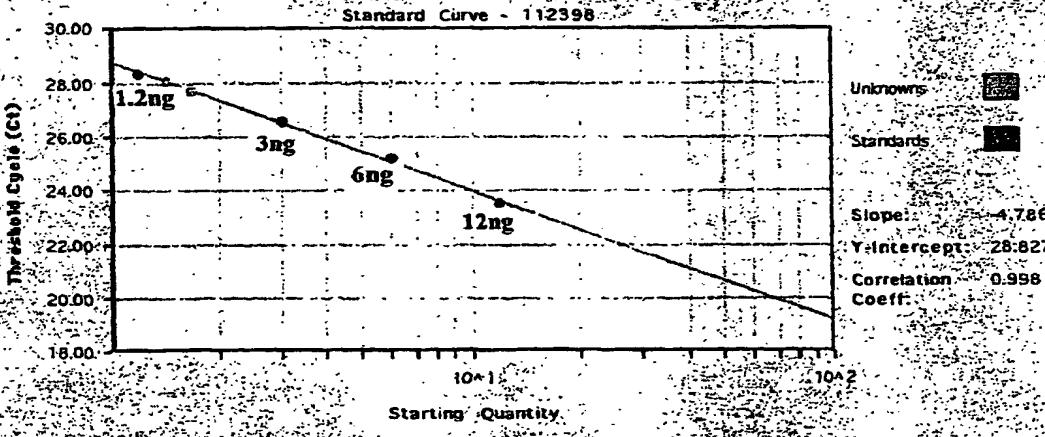
(72) Inventors; and

(75) Inventors/Applicants (for US only): BELLY, Robert, T. [US/US]; 1144 Ohstrom Park, Webster, NY 14580 (US).

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: RAPID AND EFFICIENT CAPTURE OF DNA FROM SAMPLE WITHOUT USING CELL LYSING REAGENT

Standard Curve for DNA as Evaluated by TaqMan Amplification
with the β -actin Gene after 40 PCR cycles



WO 00/66783 A3

(57) Abstract: Nucleic acids can be made available for amplification or other treatment after admixture of a sample with specific weakly basic polymers to form a precipitate with the nucleic acids at acidic pH. After removing non-precipitated materials, the pH is then made basic, thereby releasing the nucleic acids from the polymer. This method for preparing specimen samples is simple and quite rapid, and the released nucleic acids can be further treated in hybridization assays or amplification procedures. No surfactant or other cell lysing reagents are employed. The weakly basic polymers are water-soluble and cationic at acidic pH, but neutral in charge at basic pH.

INTERNATIONAL SEARCH REPORT

Inte [REDACTED] Application No
PCT/US 00/11651A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 C12Q1/68

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 C12Q

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, MEDLINE, BIOSIS, EMBASE, CHEM ABS Data, STRAND

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 97 34015 A (PENN STATE RES FOUND) 18 September 1997 (1997-09-18) cited in the application see whole doc. esp. page 37, 1.5 ff., 1.18ff. and claims ---	1-9
A	WO 95 16792 A (STROUN MAURICE ;ANKER PHILIPPE (CH); VASIOUKHIN VALERI (US)) 22 June 1995 (1995-06-22) see whole doc. esp. claims and p.3 expl. 1 ---	1-9
A	EP 0 707 077 A (JOHNSON & JOHNSON CLIN DIAG) 17 April 1996 (1996-04-17) see whole doc. esp. p. 3, 1. 20 ff., claims and examples ---	1-9 -/-

 Further documents are listed in the continuation of box C. Patent family members are listed in annex.

* Special categories of cited documents :

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- *E* earlier document but published on or after the international filing date
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- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

- *&* document member of the same patent family

Date of the actual completion of the international search

3 May 2001

Date of mailing of the international search report

14.05.01

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INTERNATIONAL SEARCH REPORT

Int'l Application No
PCT/US 00/11651

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	ANKER P. ET AL.,: "K-ras mutations are found in DNA extracted from the plasma of patients with colorectal cancer" GASTROENTEROLOGY, vol. 112, no. 4, 1997, pages 1114-1120, XP002159097 the whole document ---	1-9
X	WO 96 15262 A (DZIEGLEWSKA HANNA EVA ;GAUDERNACK GUSTAV (NO); BREIVIK JARLE (NO);) 23 May 1996 (1996-05-23) see whole doc. esp. c1.3 ---	10-22
X	GB 2 327 497 A (ZENECA LTD) 27 January 1999 (1999-01-27) see whole doc tab.17a, p.27 ---	10-22
X	WO 96 32500 A (JOHNSON & JOHNSON RES PTY LTD ;TODD ALISON VELYIAN (AU)) 17 October 1996 (1996-10-17) see whole doc. esp.p.21, 1.7 ---	10-22
X	US 5 683 877 A (HSU IH-CHANG ET AL) 4 November 1997 (1997-11-04) see whole doc. esp. seq id5, col.13,1.1-7 -----	10-22

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 00/11651

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-9 (completely)

method for providing, amplifying and detecting nucleic acids from a sample without the use of a cell lysing agent by using a water-soluble weakly basic polymer

2. Claims: 10-22 (completely)

Nucleic acid primer sequences (Seq. Ids.: 1-6), diagnostic primers comprising them and kit containing them for the detection of K-ras mutations.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inte... the application No

PCT/US 00/11651

Patent document cited in search report	Publication date	Patent family member(s)			Publication date
WO 9734015	A 18-09-1997	AU 2324997 A	01-10-1997		
		CA 2248981 A	18-09-1997		
		EP 0929694 A	21-07-1999		
		US 6156504 A	05-12-2000		
WO 9516792	A 22-06-1995	CH 686982 A	15-08-1996		
		AU 1075695 A	03-07-1995		
		GB 2299166 A, B	25-09-1996		
		US 5952170 A	14-09-1999		
EP 0707077	A 17-04-1996	US 5582988 A	10-12-1996		
		AU 706641 B	17-06-1999		
		AU 3030295 A	28-03-1996		
		CA 2158485 A	16-03-1996		
		FI 954331 A	16-03-1996		
		JP 8173194 A	09-07-1996		
		NO 953631 A	18-03-1996		
WO 9615262	A 23-05-1996	AU 704784 B	06-05-1999		
		AU 3851495 A	06-06-1996		
		CA 2205017 A	23-05-1996		
		EP 0791074 A	27-08-1997		
		JP 10508746 T	02-09-1998		
		US 6090546 A	18-07-2000		
GB 2327497	A 27-01-1999	WO 9904037 A	28-01-1999		
WO 9632500	A 17-10-1996	AU 698157 B	22-10-1998		
		AU 5260996 A	30-10-1996		
		BR 9604814 A	09-05-2000		
		CA 2218026 A	17-10-1996		
		CN 1185181 A	17-06-1998		
		EP 0871767 A	21-10-1998		
		JP 11503027 T	23-03-1999		
		ZA 9602941 A	04-12-1996		
US 5683877	A 04-11-1997	AU 3919293 A	08-11-1993		
		WO 9320233 A	14-10-1993		